K00 3141 Page 1 & +

# PARADIGM MEDICAL INDUSTRIES INC.,

2355 South 1070 West Salt Lake City, Utah 84119 (801) 977-8970 (801) 977-9043 (fax)

Tracy S. Best, Manager, Regulatory Affairs & Quality Assurance

Preparation Date: 10/09/00

# Summary of Safety and Effectiveness for the:

Trade Name:

UBM Plus, Model P45

Common Name:

Ultrasound Echo Imaging System

Classification Name:

System, Imaging, Pulsed Echo, Ultrasonic

# Legally Marketed Predicate Devices for Substantial Equivalence:

\* K923348, A/B Scan, Model 835 - Humphrey Instruments

\* K923211A, Ophthalmic Ultrasound BioMicroscope, Model UBM - Humphrey Instruments

Rationale for SE: The aforementioned devices share similar indications for use, and identical design features including; chassis, PCBA's, power supplies, etc. Control systems such as footswitch, trackball, and thermal graphic printer including displays are available for user intervention. Functional features such as; A-Scan, A-Diagnostic, B-Scan and Ultrasonic BioMicroscope are also identical to the aforementioned devices. Also see Attachment "A" Comparison Chart of Equivalence.

### **Description of Submitted Device:**

The UBM *Plus* an instrument used in the application of Diagnostic Ophthalmology Echo Imagery and produces an image by a pulsed sound beam technology that determines the depth of tissues within the eye. The image captured from the interpreted signal is then displayed on the monitor supplied with the device. With an integrated transducer and frequencies of 8, 10, and 50 MHz, the UBM *Plus* is the ideal instrument for diagnostician in Ophthalmology.

### **Intended Uses of the Elite Family Lasers:**

See attachment "B" for a complete listing of indicated uses (applied for).

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# Technological Characteristics and Substantial Equivalence:

The UBM from Humphrey Instruments was cleared under the 510(k) number K923211A utilizing the equivalent 50 MHz transducer probe suspended on a gantry arm. The UBM is able to display a quality two-dimensional image of the Anterior Segment of the eye for the detection and evaluation of anterior segment tumors, anterior angle glaucoma as well as other structures of the anterior chamber. This technology has remained basically unchanged since the initial release by Humphrey Instruments.

The A/B Scan from Humphrey Instruments was cleared under the 510(k) number K983348. The initial release of this product was the Model 835. Humphrey Instruments later added the ability to utilize a Diagnostic A Probe that produces A-Scan images with a specific signal processing for diagnostic capabilities, having a transducer frequency of 8 MHz. Since this change was documented under their quality system, and it was similar to the A-Scan Probe of 10 MHz. A letter to file documenting the change, including renaming it to the 837, and therefore, Humphrey Instruments did not file a new 510(k).

Paradigm Medical Industries acquired the rights to these products in 1998 and has manufactured them since. The UBM *Plus*, Model P45 is the combination of the two products mentioned above. The Humphrey Model 840 is the Paradigm Model P40. The Humphrey Model 837 is the Paradigm Model P37. By combining the technologies of these two devices on the same chassis, and incorporating the same power supply, PCBA's, and similar software, etc., we feel that the UBM *Plus*, Model P45 is substantially equivalent to the aforementioned devices. Because of the simplicity of the creation of the new model, a "Special (30-day) 510(k)" is warranted.

### Conclusion:

The UBM *Plus*, Model P45 is substantially equivalent to products already on the market and approved for use in Ophthalmology. By incorporating the proven safety and effectiveness of these two devices into one, the P45 is equally safe and effective.

# Comparison Table of Ultrasound Devices

	Paradigm Medical UBM <i>Plus</i> , Model P45	Humphrey Instruments Digital Ophthalmic UBM	Humphrey Instruments A/B Scan, Model 835
Transducer(s) and Power	A-Scan, 10 MHz Diagnostic A, 8 MHz B-Scan, 10 MHz Ultrasonic BioMicroscope, 50 MHz	Ultrasonic BioMicroscope, 50 MHz	A-Scan, 10 MHz Diagnostic A, 8 MHz B-Scan, 10 MHz
Cooling System	Forced Air Cooling, Dual fan system	Forced Air Cooling, Dual fan system	Forced Air Cooling
Scan Characteristics	Scan Rate of 8 Hz (13 or 18 MHz B-Scan) Sampling Resolution of 5μm Scan Width 5mm (UBM) Scan Depth 5mm (UBM) 0-60mm (others) Scan Angle (B-Scan) 40° & 60° Selectable	Scan Rate of 8 Hz Sampling Resolution of 5µm Scan Width 5mm Scan Depth 5mm	13 or 18 MHz B-Scan Sampling Resolution of 5µm Scan Angle (B-Scan) 40° & 60°, Selectable Scan Depth 0-60mm
Electrical Specifications	110 V~ or 220 V~ 50/60 Hz, 750 VA	110 V~ or 220 V~ 50/60 Hz, 750 VA	110 V~ or 220 V- 50/60 Hz, 750 VA
Display Monitor	15 inch Color CRT, Custom Display	15 inch Color CRT, Custom Display	15 inch Color CRT, Custom Display
System Control Input Devices	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port
Image Storage	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive
Dimensions/Wt.	15.25" X 18.25" X 7.13" 40 lbs.	15.25" X 18.25" X 7.13" 40 lbs.	15.25" X 18.25" X 7.13" 40 lbs.
510(k) Number	Pending this application	K923211A	K923348

From	Attachment	$\mathcal{B}$
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510(k) Number (if known):
Device Name: UBM Plus, Model P45
Indications For Use:
$\sqrt{\text{Ultrasound imaging of the eye}}$
$\sqrt{\text{Produce axial measurements of the eye}}$
$\sqrt{\text{Imaging the intraocular anatomy and pathology of the eye}}$
√Imaging the anterior segment of the eye
√Imaging the anterior angle for Glaucoma Management
√ Imaging of other structures of the anterior chamber
√Acquire and view real-time high resolution images of the anterior segment under magnification that produces a multi-dimensional
view of the eye for diagnostic evaluation
view of the eye for diagnostic evaluation
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

DEC - 5 2000

Ms. Tracy S. Best
Manager, Regulatory Affairs
and Quality Assurance
Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119

Re: K003141

P45 UBM Plus

Regulatory Class: II 21 CFR §892.1560 Product Code: 90 IYO

Dated: November 9, 2000 Received: November 14, 2000

### Dear Ms. Best:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the P45 UBM Plus, as described in your premarket notification:

# Transducer Model Number

A-Scan 10 MHz
A-Diagnostic 8 MHz
B-Scan 10 MHz
Biomicroscope 50 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97).

## Page 3 – Ms. Tracy Best

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Sprint in begion

Center for Devices and

Radiological Health

**Enclosures** 

Intended Use: D	Diagnostic ultrasound imaging or f	luid flow a	nalysis c	of the hun	nan body a	follows:	
	inical Application			Mo	de of Oper	ation	Otherst
General	Specific	B-Scan	PWD	CWD	A-Scan	_A-Diagnostic	Other* (Specify)
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	Fetal			1			
	Abdominal			<u> </u>			
	Intra-operative (Specify)						
	Intra-operative (Neuro)		<u> </u>				
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Fetal Imaging	Pediatric						
& Other	Small Organ (Specify)	<u> </u>	ļ			.4 5.74	, pis 11
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Peripheral	Peripheral vessel						
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510(k) Number

Prescription Use (Per 21 CFR 801.109)

	Diagnostic ultrasound imaging or fi inical Application			Mo	de of Oper	ation	
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<u> </u>	Fetal						
	Abdominal						· · · · · · · · · · · · · · · · · · ·
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	Intra-operative (Neuro)						
	Laparoscopic						
Fetal Imaging	Pediatric						
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Additional Cor	nmeno:						

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number 603/4/

Prescription Use (Per 21 CFR 801.109)

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Other (Specify)  Cardiac Adult  Cardiac Pediatric  Trans-esoph. (Cardiac)  Other (Specify)	Other (Specify)  Cardiac Adult  Cardiac Pediatric  Trans-esoph. (Cardiac)  Other (Specify)  Peripheral  Vessel  Other (Specify)  Other (Specify)						42. 8	Maria Cara Maria Cara Cara Cara Cara Cara Cara Cara	A Company
Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)	Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)  Peripheral Vessel Other (Specify)  Trans-esoph. (Cardiac) Other (Specify)								
Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)	Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)  Peripheral Vessel Other (Specify)  Trans-esoph. (Cardiac) Other (Specify)								<del> </del>
Trans-esoph. (Cardiac) Other (Specify)	Trans-esoph. (Cardiac) Other (Specify)  Peripheral Vessel Other (Specify)  Trans-esoph. (Cardiac) Other (Specify)	C						1 New York 1 1 1 21 4 6	
Other (Specify)	Other (Specify)  Peripheral Vessel  Vessel Other (Specify)  Other (Specify)	Cardiac							
	Peripheral Peripheral vessel  Vessel Other (Specify)								
Peripheral Peripheral vesser	Vessel Other (Specify)								
	The Foundary Amoundity E	-							
The Foundary Amoundity F	N= new indication; P= previously cleared by PDA, E= added united Harmonic Imaging, Tissue Motion Dopple			- DΔ · F = 2	dded ur	der App	endix E		
*Examples may include: A-mode, Amplitude Dopplet, C. S. Maria Include: A-mode, Amplitude: A-mode, Amplitude Dopplet, C. S. Maria Include: A-mode, Amplitude: A-mode, Amplitude Dopplet, C. S. Maria Include: A-mode, Amplitude		Color Velocity	magnig						
*Examples may include: A-mode, Amplitude Dopplet, Color Velocity Imaging	Color Velocity Imaging	A 183 -1C-	mana amto.						
Color Velocity Imaging		Additional Co	mmenu:						
*Examples may include: A-mode, Amplitude Dopplet, C Data S, Color Velocity Imaging  Additional Comments:									

Prescription Use (Per 21 CFR 801.109)

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General Track I Only)	ical Application Specific			f the hun	de of Opera	1000	
			PWD	CWD			Other*
HINCK I CHILY/	(Tracks 1 & III)	B-Scan			A-Scan	A-Diagnostic	(Specify)
Ophthalmic	Ophthalmic	N					
	Fetal						
L.	Abdominal						
	Intra-operative (Specify)						
· -	Intra-operative (Neuro)						<u>i</u>
	Laparoscopic						
	Pediatric					1.00	
COLI	Small Organ (Specify)				4.		
	Neonatal Cephalic		<del>                                     </del>			Liver of Contra	. 4.
-	Adult Cephalic		<del>                                     </del>		7.0 N.	The second second second second	94.95, A
ŀ	Trans-rectal		<del> </del>				
1	Trans-vaginal	<del></del>	<del> </del>	1			
1	Trans-urethral	<u> </u>	1				
	Trans-esoph. (non-Card.)	<b> </b>	1				
•	Musculo-skel. (Conventional)	<del> </del>	-	1		2000 (2) 10 - 10 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	3 327
	Musculo-skel. (Superficial)	<del> </del>	1			·	
	Intra-luminal				no replicate	Marie Committee and the second processing of t	· John State Committee
	Other (Specify)	<u> </u>			+		
	Cardiac Adult	<u> </u>					1
Cardiac	Cardiac Pediatric	ļ		<del></del>	<del>-</del>		
	Trans-esoph. (Cardiac)				ļ		
	Other (Specify)	<u> </u>			<u> </u>		
Peripheral	Peripheral vessel				<u>   </u>		<del></del>
Voccol	Other (Specify) on; P= previously cleared by F						

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

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510(k) Number <u>503141</u>

Clin General				Mo	nan body as de of Oper	ation	Other*
Campus	ical Application		PWD	CWD		A-Diagnostic	(Specify
	Specific	B-Scan			A-Scan	A-Diagnosuc	(opton)
Track I Only)	(Tracks 1 & III)	N					
Ophthalmic	Ophthalmic						
	Fetal		<del>                                     </del>				
1	Abdominal		<del> </del>	-			<u> </u>
j	Intra-operative (Specify)		<del> </del>	<del> </del>			
Ì	Intra-operative (Neuro)		<del> </del>	+			<u> </u>
	Laparoscopic		<del> </del>	-}		44 D	
etal Imaging	Pediatric		<del>                                     </del>				
etai iiilagiiig 81 Other	Small Organ (Specify)	<u> </u>	<b></b>	<del> </del>			
& Other	Neonatal Cephalic	<u> </u>		<b>-</b>	<del> </del>		
	Adult Cephalic				<del> </del>		
	Trans-rectal				770.4	.550/	1
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						<del></del>
	Musculo-skel. (Conventional)						<del> </del>
	Musculo-skel. (Superficial)						_
		1					
	Intra-luminal	1			11,000	1938 Day Day of Co.	
	Other (Specify)						
	Cardiac Adult	╂			76 J. 776	e water the contract of the co	
Cardiac	Cardiac Pediatric					•	
	Trans-esoph. (Cardiac)		<del>-1</del>				
	Other (Specify)					The second of the	1. P.O
Peripheral	Peripheral vessel						
	Other (Specify)				25- 8"		

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510(k) Number 6003/4/

Prescription Use (Per 21 CFR 801.109)